

## Instructions for Use: ChannelCheck™ Convenience Pack

<b>Brand Name of Product</b>	ChannelCheck™ Convenience Pack
<b>Generic Name of Product</b>	3-in-1 Residual Soil Test Kit
<b>Product Code Number(s)</b>	UCC-222CP, UCC-222TS, ATS-2-CTP
<b>Intended Use</b>	To check internal channels of lumened items for residual protein, blood, and carbohydrates.
<b>Range of Applications for Product</b>	Internal channels that come in contact with protein, blood, and/or carbohydrate during clinical use.
<b>Key Specifications of Product</b>	Sensitivity of Reagent Pads: <ul style="list-style-type: none"> <li>• Carbohydrate <math>\geq 25 \mu\text{g/mL}</math></li> <li>• Protein <math>\geq 30 \mu\text{g/mL}</math></li> <li>• Hemoglobin <math>\geq 0.25 (1/4) \mu\text{g/mL}</math></li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	Avoid direct sunlight.
<b>Storage Conditions</b>	<ul style="list-style-type: none"> <li>• Box should be kept closed.</li> <li>• Keep in a cool, dry place out of direct sunlight.</li> </ul>
<b>Packaging Contents</b>	<ul style="list-style-type: none"> <li>• Fifty (50) UCC-222 Test Strips (individually packaged)</li> <li>• One (1)-ATS Control Vial</li> <li>• Fifty (50) Zipper Bags (2- x 3 inches) for collection</li> <li>• Fifty (50) Prefilled 10 mL Water Syringes</li> <li>• Two (2) Interpretation Guides</li> <li>• One (1)-IFU</li> <li>• UCC-222TS (Water syringes are not provided).</li> </ul>
<b>Shelf Life</b>	Convenience Pack has a shelf life of 18 months.

Instructions for Using Product	
<b>Description of Use(s)</b>	N/A
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>• The UCC-222CP is packaged as 5 boxes of 10 bags. <ul style="list-style-type: none"> <li>○ These are labeled “1 of 5 box”, “2 of 5 box” ... “5 of 5 box”.</li> <li>○ Separating the boxes allows one box to be used at a time and the other boxes to be stored until needed.</li> </ul> </li> <li>• Box 1 states, “This box contains the control test, control test must be run first.” The control test is the first bag when Box 1 is opened that says, “Under the control test are nine (9) ea. HPC-222CP, individually wrapped ChannelCheck™, a syringe, and a 2- x 3 inches zipper bag.”</li> <li>• Boxes 2–5 have 10 HPC-222CP.</li> </ul> <p>First, run the control test (before any test) to ensure shipping and storage conditions did not impact or harm the other tests. (NOTE: Testing must be conducted after cleaning and prior to disinfection/sterilization.)</p> <ol style="list-style-type: none"> <li>1. <b>Control Test:</b> The first step is to check performance with the included vial of control soil. (NOTE: This is only done with one of the individually packaged test strips and 1-ATS control vial that is included in the Convenience Pack.) <ol style="list-style-type: none"> <li>a. Remove the test vial of dehydrated test soil from the package.</li> <li>b. The test vial holds enough lyophilized test soil to create a single milliliter of test soil.</li> </ol> </li> <li>2. <b>Rehydrate Soil:</b> To rehydrate, a) unscrew the cap from the vial, b) add exactly 1-mL of prepackaged chlorine-free water to the vial, then c) screw the cap back on the vial ensuring you have a tight seal.</li> <li>3. <b>Shake Vigorously:</b> Shake the vial vigorously for at least 1-minute. Check the vial to make sure the soil has been completely rehydrated.</li> <li>4. <b>Retrieve a Single Test Strip:</b> Retrieve a single ChannelCheck™ test strip from the pack.</li> </ol>

5. **Dip Test Strip into Vial:** Dip the test into the vial for 5 seconds. (NOTE: Make sure to completely immerse all 3 test pads into the solution.)
6. **Dab Side of Test Strip on Absorbent Pad:** After 5 seconds, remove the test strip and dab the side of the moistened test pad on a clean, dry absorbent pad to wick off excess water.
7. **Wait 5 Minutes:** The reagents in the test pads require time to interact with the residual soil. Wait a complete 5 minutes before reading the results.
8. **Compare Results to Control Color Chart:** Compare the results to the “Control Color Chart”. (NOTE: The colors of each test pad should closely approximate the colors on the “Control Color Chart” found in the “Interpretation Guide”.)
9. **Record Results:** On a log sheet, record the results of each pad.

**Diagrams (drawings, pictures)**



ChannelCheck™ Convenience Pack



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 5a





Figure 6



Figure 6a



Figure 7

		
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Uncap prefilled 10 mL water syringe.</li> <li>2. <b>Flush the Water Through Channel:</b> Performed by flushing the item's channel(s): <ol style="list-style-type: none"> <li>a. Remove the white cap from the tip of the 10 mL prepackaged chlorine-free water syringe. (Fig. 4).</li> <li>b. Attach the Slip Tip Adapter to the tip of the 10 mL prepackaged chlorine-free water syringe, and twist to secure. (Fig. 5, 5a).</li> <li>c. Place the slip tip at the channel to be tested and use the plunger-rod to deliver the water to sample the channel. (Fig. 6, 6a).</li> <li>d. Flush with 10 mL of prepackaged chlorine-free water.</li> <li>e. Refill with air to finish the sampling procedure.</li> <li>f. Followed by 10 mL of air to facilitate flushing.</li> </ol> </li> <li>3. <b>Recapture Water in the Zipper Bag:</b> Recapture the water in a clean zipper bag (see "Zipper Bag Sample Collection" instructions in the <i>Additional Information</i> section below). (Fig.7).</li> <li>4. <b>Dip Test Strip into Water:</b> Dip the test strip into the recaptured water, ensuring all 3 pads are completely immersed. Keep the test strip immersed for 5 seconds. (Fig. 8).</li> <li>5. <b>Dab Side of Test Strip:</b> Remove test strip from the water and dab its side on a clean, absorbent surface to wick away excess water.</li> <li>6. <b>Wait 90 Seconds:</b> The reagents in the test pads require time to interact with the residual soil. Wait a complete 90 seconds before reading the results. (Fig. 9).</li> </ol>	
<b>Interpretation of Results</b>	<ol style="list-style-type: none"> <li>1. <b>Compare to Color Chart:</b> Compare test strip to the "No Residue Color Chart" found on the Interpretation Guide to interpret results.</li> <li>2. <b>Interpret Results:</b> If the colors on any pad deviate from the "No Residue Color Chart", this indicates a soiled item and should be recleaned and retested until test results match the "No Residues Color Chart".</li> </ol>	
<b>Contraindications of Test Results</b>	<ul style="list-style-type: none"> <li>● Residual peracetic acid-based disinfectants may interfere with the carbohydrate and blood pads of the ChannelCheck™.</li> <li>● Oxidizing agents (e.g., chlorine or hypochlorite) may produce a color change on the hemoglobin pad. (NOTE: These residues should <i>not</i> remain on an item that has been properly rinsed.</li> <li>● Excess residual Intercept® (brand of Cantel Medical) detergent can cause a color change on the protein pad. (NOTE: Adequate rinsing is advised to remove any excess detergent prior to testing with ChannelCheck™.)</li> <li>● Sterile water with adhered foil lids should not be used because of potential reaction with the carbohydrate pad.</li> <li>● Sani-Cloth® and CaviWipes™ may cause color change in the protein pad.</li> </ul>	
<b>Documentation</b>	<b>Record results of each pad on a log sheet.</b>	
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>● Perform rinsing after manual cleaning to remove residual contaminants and detergent prior to performing the ChannelCheck™.</li> <li>● ChannelCheck™ does not ensure an item is safe for use or free of contamination. It is to be one-step in a total quality process implemented by the healthcare facility to verify the cleaning process.</li> <li>● Do not swirl the strip when dipping in the water. Swirling can cause color to run off the pad and change the results.</li> <li>● <b>IMPORTANT:</b> Protect the test strips from ambient moisture, light, and heat to guard against altered reagent activity and deterioration.</li> </ul>	

	<ul style="list-style-type: none"> <li>Some reagents (in any one of the pads) could release when immersed in water and slightly color the water. This is normal and will not adversely affect the performance of the test.</li> </ul>
<b>Disposal</b>	It is recommended to dispose of the used test strip in a suitable biohazard container.

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	N/A

<b>Additional Information</b>	<p><b>Zipper Bag Sample Collection:</b></p> <ol style="list-style-type: none"> <li>Open the clean plastic zipper bag by gently pushing from the side of the bag. (Fig. 1). This creates a wide enough opening for the clean plastic zipper bag to be placed over the distal tip.</li> <li>Push the distal tip halfway down into the clean plastic zipper bag. (Fig. 2). <ol style="list-style-type: none"> <li>Seal the bag by pushing the sides together.</li> <li>Close the zipper seal about three-quarters of the way (up to the distal tip) and then stop. (NOTE: This will provide enough of a seal to capture the sample without the bag falling off during the sampling process.) (Fig. 3).</li> </ol> </li> <li>Follow instructions found in <i>Steps for Use of Product</i>.</li> </ol>
<b>Related Healthmark Products</b>	ATS
<b>Other Product Support Documents</b>	Cleaning Verification Brochure, Cleaning Verification Price List, ChannelCheck™ Specification Sheet, ChannelCheck™ Bottle Label, ChannelCheck™ Packaging Insert, ChannelCheck™ Validation Study, Instructions for Residual Soil Tests, Sample Policy with competency for ChannelCheck™, MSDS ChannelCheck™ UCC-222.
<b>Reference Documents</b>	<ul style="list-style-type: none"> <li>ALFA MJ, DEGAGNE P, AND OLSON N. WORST-CASE SOILING LEVELS FOR PATIENT-USED FLEXIBLE ENDOSCOPES BEFORE AND AFTER CLEANING. AM J INFECT CONTROL, 27:392–401, 1999.</li> <li>ALFA MJ, DEGAGNE P, AND OLSON N. VALIDATION OF ATS AS AN APPROPRIATE TEST SOIL. ZENTR STERIL, 13(6):387–402, 2005.</li> <li>ALFA MJ, OLSON N, DEGAGNE P, AND JACKSON M. A SURVEY OF REPROCESSING METHODS, RESIDUAL VIABLE BIOBURDEN AND SOIL LEVELS IN PATIENT-READY ENDO-SCOPIC RETROGRADE CHOLIANGIOPANCREATOGRAPHY DUODENOSCOPES USED IN CANADIAN CENTERS. INFECT CONTROL HOSP EPIDEMIOL, 23:198–206, 2002.</li> </ul>
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